

Message

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**From:** Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]  
**Sent:** 4/24/2018 2:20:38 PM  
**To:** Schwab, Justin [schwab.justin@epa.gov]  
**Subject:** FW: For Review: Science Transparency News Release

**Erik Baptist**

Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)

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**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 10:12 AM  
**To:** Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

A few minor edits below – Deletions ~~struck through~~ and additions in yellow. Thanks!

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**From:** Woods, Clint  
**Sent:** Monday, April 23, 2018 6:14 PM  
**To:** Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** Re: For Review: Science Transparency News Release

Thanks so much! Will send over a few small edits. Agree with Richard. Two other quick thoughts:

## Ex. 5 Deliberative Process (DP)

On Apr 23, 2018, at 5:53 PM, Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)> wrote:

(This Email contains predecisional and deliberative matters)

# Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Attached, and below, please find a draft press release, based on the talking points and including the statements of support Clint gathered. I am adding Christian/Aaron, to see if they have any additional support statements from Members of Congress that we could add. I wasn't sure about the quotes from scientific journals, but I think they add weight to the announcement. Also, assuming that this will link to the proposal. The current plan is to release shortly following the event, with photos. The event will be live streamed. Please add anyone else I forgot to copy who should be in the loop. Thank you – Liz

## Ex. 5 Deliberative Process (DP)

## **Ex. 5 Deliberative Process (DP)**

# **Ex. 5 Deliberative Process (DP)**

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Message

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**From:** Bowman, Liz [Bowman.Liz@epa.gov]  
**Sent:** 4/24/2018 5:25:42 PM  
**To:** Schwab, Justin [Schwab.Justin@epa.gov]  
**CC:** Baptist, Erik [Baptist.Erik@epa.gov]  
**Subject:** RE: For Review: Science Transparency News Release

Thank you

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**From:** Schwab, Justin  
**Sent:** Tuesday, April 24, 2018 12:40 PM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>  
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>  
**Subject:** Re: For Review: Science Transparency News Release

I'd have Clint check it one more time to make sure but I don't see any.

Sent from my iPhone

On Apr 24, 2018, at 11:14 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Thank you all – does this include any updates with regard to the edits received from OMB today (I understand they are pretty significant).

---

**From:** Baptist, Erik  
**Sent:** Monday, April 23, 2018 6:00 PM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>  
**Cc:** Schwab, Justin <[Schwab.Justin@epa.gov](mailto:Schwab.Justin@epa.gov)>  
**Subject:** FW: For Review: Science Transparency News Release

Liz,

Justin's edits are attached.

**Erik Baptist**  
Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
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(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)

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**From:** Schwab, Justin  
**Sent:** Monday, April 23, 2018 5:55 PM  
**To:** Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

Redline attached.

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**From:** Baptist, Erik  
**Sent:** Monday, April 23, 2018 5:46 PM  
**To:** Schwab, Justin <[Schwab.Justin@epa.gov](mailto:Schwab.Justin@epa.gov)>  
**Subject:** FW: For Review: Science Transparency News Release

Please review. Thanks!

**Erik Baptist**  
Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)

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**Sent:** Monday, April 23, 2018 5:37 PM  
**To:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>  
**Cc:** Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** For Review: Science Transparency News Release

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## Ex. 5 Deliberative Process (DP)

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**From:** Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]  
**Sent:** 4/24/2018 6:14:11 PM  
**To:** Schwab, Justin [schwab.justin@epa.gov]  
**Subject:** FW: For Review: Science Transparency News Release  
**Attachments:** 2018-04-24 DRAFT News Release re Science Transparency.docx

**Erik Baptist**

Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)

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**From:** Bowman, Liz  
**Sent:** Tuesday, April 24, 2018 2:03 PM  
**To:** Palich, Christian <palich.christian@epa.gov>; Ringel, Aaron <ringel.aaron@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
**Subject:** RE: For Review: Science Transparency News Release

Attached, and below, please find the updated release – we plan to send this out shortly

## **EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent that underlying scientific information is publicly available in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s *Science for Policy Project* and the Administrative Conference of the United States’ *Science in the Administrative Process Project*.

The proposed rule builds upon President Trump's executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility."
- **Executive Order 13783**, also issued in March 2017, provides that "It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

**Chairman Lamar Smith (R-TX):** "Administrator Pruitt's announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It's likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas."

**Senator Mike Rounds (R-SD):** "Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA's decisions. Today's directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected."

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** "The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process."

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** "I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy."

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** "EPA's proposed rule, Strengthening Transparency in Regulatory Science, is badly needed. "Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based."

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** "IDEM supports transparency in rulemaking. Good, sound science leads to better regulations."

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA's Clean Air Scientific Advisory Committee (1992 – 1996):** "In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and

models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

###

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**From:** Palich, Christian  
**Sent:** Tuesday, April 24, 2018 12:47 PM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>  
**Cc:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

Below is from Senator Rounds.

**“Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”**

Christian R. Palich  
*Deputy Associate Administrator*  
*Office of Congressional & Intergovernmental Affairs*  
*U.S Environmental Protection Agency*  
*O: 202.564.4944*  
*C: 202.306.4656*  
*E: [Palich.Christian@epa.gov](mailto:Palich.Christian@epa.gov)*

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**From:** Bowman, Liz  
**Sent:** Tuesday, April 24, 2018 11:17 AM  
**To:** Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>  
**Cc:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

They sent me one directly 😊 thank you!

---

**From:** Ringel, Aaron  
**Sent:** Monday, April 23, 2018 5:46 PM  
**To:** Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>

**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>

**Subject:** Re: For Review: Science Transparency News Release

Same for Chairman Smith. Will see if I can get a quote.

Sent from my iPhone

On Apr 23, 2018, at 5:38 PM, Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)> wrote:

Senator Rounds is attending, I'll reach out to see if we can get a quote from him.

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Attached, and below, please find a draft press release, based on the talking points and including the statements of support Clint gathered. I am adding Christian/Aaron, to see if they have any additional support statements from Members of Congress that we could add. I wasn't sure about the quotes from scientific journals, but I think they add weight to the announcement. Also, assuming that this will link to the proposal. The current plan is to release shortly following the event, with photos. The event will be live streamed. Please add anyone else I forgot to copy who should be in the loop. Thank you – Liz

### **EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS, ENDS 'SECRET SCIENCE'**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and will require that the underlying scientific information be publicly available, in a manner sufficient for independent validation.

"The era of secret science at EPA is coming to an end," said EPA Administrator Scott Pruitt. "The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives."

This proposed rule is in line with the scientific community's moves toward increased data sharing to address the "replication crisis," in which a significant

proportion of published research may be false or not reproducible. Examples of the current data access provisions for authors publishing in major scientific journals:

- Science: “All data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis.”
- Nature: “This policy builds upon our long-standing policy on data availability, which requires that authors make materials, data, code, and associated protocols promptly available to readers without undue qualifications. The preferred way to share large data sets is via public repositories.”
- Proceedings of the National Academy of Sciences: “To allow others to replicate and build on work published in PNAS, authors must make materials, data, and associated protocols, including code and scripts, available to readers.”

EPA’s proposal is consistent with President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, explains that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
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“The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process,” **said Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts**

“I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science,” **said Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis***. “Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

“EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed,” **said Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law**. “Best practice among peer-edited

scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

“IDEM supports transparency in rulemaking,” says **Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM)**. “Good, sound science leads to better regulations.”

“In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations,” said **Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 – 1996)**.

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<Document1.docx>

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**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** “The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process.”

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** “I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** “EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

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regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

###

**From:** Bowman, Liz [Bowman.Liz@epa.gov]  
**Sent:** 4/24/2018 6:03:22 PM  
**To:** Palich, Christian [palich.christian@epa.gov]; Ringel, Aaron [ringel.aaron@epa.gov]  
**CC:** Woods, Clint [woods.clint@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Gordon, Stephen [gordon.stephen@epa.gov]; Letendre, Daisy [letendre.daisy@epa.gov]; Konkus, John [konkus.john@epa.gov]; Beach, Christopher [beach.christopher@epa.gov]; Jackson, Ryan [jackson.ryan@epa.gov]  
**Subject:** RE: For Review: Science Transparency News Release  
**Attachments:** 2018-04-24 DRAFT News Release re Science Transparency.docx

Attached, and below, please find the updated release – we plan to send this out shortly

## **EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent that underlying scientific information is publicly available in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s *Science for Policy Project* and the Administrative Conference of the United States’ *Science in the Administrative Process Project*.

The proposed rule builds upon President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
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**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** “The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process.”

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** “I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** “EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** “IDEM supports transparency in rulemaking. Good, sound science leads to better regulations.”

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 – 1996):** “In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

###

---

**From:** Palich, Christian

**Sent:** Tuesday, April 24, 2018 12:47 PM

**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Ringel, Aaron <ringel.aaron@epa.gov>

**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John

<konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>

**Subject:** RE: For Review: Science Transparency News Release

Below is from Senator Rounds.

**“Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”**

Christian R. Palich  
*Deputy Associate Administrator*  
*Office of Congressional & Intergovernmental Affairs*  
*U.S Environmental Protection Agency*  
*O: 202.564.4944*  
*C: 202.306.4656*  
*E: [Palich.Christian@epa.gov](mailto:Palich.Christian@epa.gov)*

---

**From:** Bowman, Liz  
**Sent:** Tuesday, April 24, 2018 11:17 AM  
**To:** Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>  
**Cc:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

They sent me one directly 😊 thank you!

---

**From:** Ringel, Aaron  
**Sent:** Monday, April 23, 2018 5:46 PM  
**To:** Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>  
**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** Re: For Review: Science Transparency News Release

Same for Chairman Smith. Will see if I can get a quote.

Sent from my iPhone

On Apr 23, 2018, at 5:38 PM, Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)> wrote:

Senator Rounds is attending, I'll reach out to see if we can get a quote from him.

Christian R. Palich

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Attached, and below, please find a draft press release, based on the talking points and including the statements of support Clint gathered. I am adding Christian/Aaron, to see if they have any additional support statements from Members of Congress that we could add. I wasn't sure about the quotes from scientific journals, but I think they add weight to the announcement. Also, assuming that this will link to the proposal. The current plan is to release shortly following the event, with photos. The event will be live streamed. Please add anyone else I forgot to copy who should be in the loop. Thank you – Liz

**EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED  
IN EPA REGULATIONS, ENDS 'SECRET SCIENCE'**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and will require that the underlying scientific information be publicly available, in a manner sufficient for independent validation.

"The era of secret science at EPA is coming to an end," said EPA Administrator Scott Pruitt. "The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives."

This proposed rule is in line with the scientific community's moves toward increased data sharing to address the "replication crisis," in which a significant proportion of published research may be false or not reproducible. Examples of the current data access provisions for authors publishing in major scientific journals:

- Science: "All data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis."
- Nature: "This policy builds upon our long-standing policy on data availability, which requires that authors make materials, data, code, and associated protocols promptly available to readers without undue qualifications. The preferred way to share large data sets is via public repositories."
- Proceedings of the National Academy of Sciences: "To allow others to replicate and build on work published in PNAS, authors must make materials, data, and associated protocols, including code and scripts, available to readers."

EPA's proposal is consistent with President Trump's executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, explains that regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility."
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"The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process," said **Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts**

"I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science," said **Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis***. "Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy."

"EPA's proposed rule, Strengthening Transparency in Regulatory Science, is badly needed," said **Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law**. "Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based."

"IDEM supports transparency in rulemaking," says **Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM)**. "Good, sound science leads to better regulations."

"In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The

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<Document1.docx>

## EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS

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This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like [ [HYPERLINK "http://www.sciencemag.org/authors/science-journals-editorial-policies"](http://www.sciencemag.org/authors/science-journals-editorial-policies) ], [ [HYPERLINK "http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf"](http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf) ], and [ [HYPERLINK "http://www.pnas.org/page/authors/journal-policies"](http://www.pnas.org/page/authors/journal-policies) ] as well as recommendations from the Bipartisan Policy Center’s [ [HYPERLINK "http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fml.pdf"](http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fml.pdf) ] and the Administrative Conference of the United States’ [ [HYPERLINK "https://www.acus.gov/research-projects/science-administrative-process"](https://www.acus.gov/research-projects/science-administrative-process) ].

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regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

###

Message

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**From:** Johnson, Laura-S [Johnson.Laura-S@epa.gov]  
**Sent:** 4/24/2018 9:17:01 PM  
**To:** Brennan, Thomas [Brennan.Thomas@epa.gov]; Johnston, Khanna [Johnston.Khanna@epa.gov]; Benjamin-Sirmons, Denise [Benjamin-Sirmons.Denise@epa.gov]; Rogers, JoanB [Rogers.JoanB@epa.gov]; Showman, John [Showman.John@epa.gov]; Vizian, Donna [Vizian.Donna@epa.gov]; Wehrum, Bill [Wehrum.Bill@epa.gov]; Gunasekara, Mandy [Gunasekara.Mandy@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]; Woods, Clint [woods.clint@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bodine, Susan [bodine.susan@epa.gov]; Starfield, Lawrence [Starfield.Lawrence@epa.gov]; Traylor, Patrick [traylor.patrick@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Nishida, Jane [Nishida.Jane@epa.gov]; Cherry, Katrina [Cherry.Katrina@epa.gov]; Robbins, Chris [Robbins.Chris@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Breen, Barry [Breen.Barry@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Szaro, Deb [Szaro.Deb@epa.gov]; Lopez, Peter [lopez.peter@epa.gov]; Mugdan, Walter [Mugdan.Walter@epa.gov]; Servidio, Cosmo [Servidio.Cosmo@epa.gov]; Rodrigues, Cecil [rodrigues.cecil@epa.gov]; Glenn, Trey [Glenn.Trey@epa.gov]; Heard, Anne [Heard.Anne@epa.gov]; Stepp, Cathy [stepp.cathy@epa.gov]; Chu, Ed [Chu.Ed@epa.gov]; Idsal, Anne [idsal.anne@epa.gov]; Gray, David [gray.david@epa.gov]; Flournoy, Karen [Flournoy.Karen@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Thomas, Deb [thomas.debrah@epa.gov]; Strauss, Alexis [Strauss.Alexis@epa.gov]; Jordan, Deborah [Jordan.Deborah@epa.gov]; Hladick, Christopher [hladick.christopher@epa.gov]; Pirzadeh, Michelle [Pirzadeh.Michelle@epa.gov]; Cook, Steven [cook.steven@epa.gov]  
**CC:** Konkus, John [konkus.john@epa.gov]; Gordon, Stephen [gordon.stephen@epa.gov]; Palich, Christian [palich.christian@epa.gov]; Ringel, Aaron [ringel.aaron@epa.gov]; Stanich, Ted [Stanich.Ted@epa.gov]; Lawrence, Tanya [Lawrence.Tanya@epa.gov]; Etzel, Ruth [Etzel.Ruth@epa.gov]; Reed, Khesha [Reed.Khesha@epa.gov]; Torres, Ramon [Torres.Ramon@epa.gov]; Maher, Karen [Maher.Karen@epa.gov]; Greaves, Holly [greaves.holly@epa.gov]; Bloom, David [Bloom.David@epa.gov]; Osborne, Howard [Osborne.Howard@epa.gov]; Fine, Steven [fine.steven@epa.gov]; Simon, Harvey [Simon.Harvey@epa.gov]; Elkins, Arthur [Elkins.Arthur@epa.gov]; Sheehan, Charles [Sheehan.Charles@epa.gov]  
**Subject:** SIGNED: Strengthening Transparency in Regulatory Science  
**Attachments:** Strengthening Transparency in Regulatory Science 04-24-2018.pdf  
**Importance:** High

FYI... please read below regarding an action taken by the Administrator today.

Sincerely,  
Laura

Laura S. Johnson | U.S. Environmental Protection Agency  
Special Assistant, Office of the Administrator | Cell (202) 819-4941  
Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

---

**From:** Johnson, Laura-S  
**Sent:** Tuesday, April 24, 2018 3:10 PM  
**To:** Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>  
**Cc:** Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William

<Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>

**Subject:** SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon

Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,  
Laura

Laura S. Johnson | U.S. Environmental Protection Agency  
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Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 30**

**[EPA-HQ-OA-2018-0259; FRL-XXXX-XX]**

**RIN 2080-AA14**

**Strengthening Transparency in Regulatory Science**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

**DATES:** Comments must be received on or before **[insert date 30 days after date of publication in the Federal Register]**.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OA-2018-0259, at [https:// www.regulations.gov](https://www.regulations.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a

written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION, CONTACT:** Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-0221; email address: [staff\\_osa@epa.gov](mailto:staff_osa@epa.gov).

**SUPPLEMENTARY INFORMATION:**

*Submitting CBI.* Do not submit information that you consider to be CBI electronically through <https://www.regulations.gov> or email. Send or deliver information identified as CBI to only the following address using U.S. Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA-HQ-OA-2018-0259, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For other methods of delivery, see <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

*Organization of This Document.* The following outline is provided to aid in locating information in this preamble.

- I. General Information
  - A. Does this Action Apply to Me?
  - B. What action is the Agency taking?
  - C. What is the Agency's Authority for taking this action?
- II. Background
- III. Request for Comment
- IV. Statutory and Executive Orders

**I. General Information**

*A. Does this action apply to me?*

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

*B. What action is the agency taking?*

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

*C. What is the agency's authority for taking this action?*

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048;



Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

## **II. Background**

The best available science must serve as the foundation of EPA's regulatory actions.<sup>1</sup> Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency is enhancing the public's ability to understand and meaningfully participate in the regulatory process.<sup>2</sup> In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models

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<sup>1</sup> See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

<sup>2</sup> See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

underlying scientific studies that are pivotal to the regulatory action are available to the public.

This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.<sup>3</sup> This proposed rule is also consistent with Executive Orders 13777<sup>4</sup> and 13783,<sup>5</sup> and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*<sup>6</sup> (the Guidelines) and OMB *Memorandum 13-13: Open Data Policy—Managing Information as an Asset*.<sup>7</sup> It builds upon prior EPA actions<sup>8</sup> in response to government-wide data access and sharing policies, as well as the experience of other

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<sup>3</sup> EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. See *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

<sup>4</sup> Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

<sup>5</sup> Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

<sup>6</sup> February 22, 2002 (67 F.R. 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) <https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information>.

<sup>7</sup> *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* (<https://project-open-data.cio.gov/policy-memo/>). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

<sup>8</sup> *Plan to Increase Access to Results of EPA-Funded Scientific Research*; *EPA Open Government Plan 4.0*; *Open Data Implementation Plan*; *EPA's Scientific Integrity Policy*; *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*; 7

federal agencies in this space.<sup>9</sup> In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.<sup>10</sup> These policies are informed by the policies recently adopted by some major scientific journals,<sup>11</sup> spurred in some part by the “replication crisis.”<sup>12</sup>

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling “pivotal regulatory science.” “Pivotal regulatory science” is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory

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<sup>9</sup> For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (<https://www.census.gov/fsrdc>).

<sup>10</sup> These include policies and recommendations from: the Administrative Conference of the United States’ Science in the Administrative Process Project; National Academies’ reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21<sup>st</sup> Century; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center’s Science for Policy Project.

<sup>11</sup> For example, see related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature.

<sup>12</sup> See: <https://www.nature.com/articles/s41562-016-0021>;  
<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124>;  
<http://science.sciencemag.org/content/343/6168/229.long>; <https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong>;  
<http://stm.sciencemag.org/content/8/341/341ps12.full>

science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying “pivotal regulatory science”) is available to the public for validation<sup>13</sup> in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis. Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA’s regulatory science should be consistent with the Office of Management and Budget’s *Final Information Quality Bulletin for Peer Review*.<sup>14</sup> Robust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-

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<sup>13</sup> EPA has not consistently followed previous EPA policy (e.g., EPA’s Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

<sup>14</sup> <https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf>

linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: a broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines<sup>15</sup> (which apply to "third party" information - e.g., non-government scientific research – if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of

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<sup>15</sup> February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) <https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information>

the Federal government.<sup>16</sup> Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.<sup>17</sup> The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that “Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.”<sup>18</sup> More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy<sup>19</sup> have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,<sup>20</sup> to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.<sup>21</sup> EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective

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<sup>16</sup> See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

<sup>17</sup> <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>.

<sup>18</sup> <https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities>.

<sup>19</sup> <https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf>.

<https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy>; <https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps>.

<sup>20</sup> For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature.

<sup>21</sup> For example: <https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/>; <https://www.census.gov/fsrdoc>.

and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.<sup>22</sup>

Implementation of this proposed rule will be consistent with the definition of “research data” in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be “significant regulatory actions” pursuant to E.O. 12866. The Agency’s offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

### **III. Request for Comment**

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other

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<sup>22</sup>These recommendations are consistent with those of Lutter and Zorn (2016).  
<https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf>.we re

policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above. EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate. Although the proposed regulatory text would impose requirements specifically on final regulations determined to be “significant regulatory actions” under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be “major” under the Congressional Review Act, or “economically significant” under EO 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant



final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of “*pivotal regulatory science*,” and “*dose response data and models*” and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies’ policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future

significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

#### **IV. Statutory and Executive Orders Reviews**

##### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:*

###### *Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies<sup>23</sup> This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy,

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<sup>23</sup> <https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities>.

confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to EO 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: “Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. ...” They concluded that “an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available.”<sup>24</sup>

*B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is not expected to be an Executive Order 13771 regulatory action because it relates to “agency organization, management or personnel.”

*C. Paperwork Reduction Act (PRA)*

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

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<sup>24</sup> <https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf>.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

*J. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority*

*Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

**List of Subjects in 40 CFR Part 30**

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements

Dated: \_\_\_\_\_

APR 24 2018

A handwritten signature in black ink, appearing to read "E. Scott Pruitt", is written over a horizontal line. The signature is stylized with a large, sweeping initial "E" and a long horizontal stroke extending to the right.

E. Scott Pruitt,

Administrator

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

**PART 30—Transparency in Regulatory Decisionmaking**

1. Add part 30 to read as follows:

**PART 30—Transparency in Regulatory Decisionmaking**

Sec.

- 30.1 What is the purpose of this subpart?
- 30.2 What definitions apply to this subpart?
- 30.3 How do the provisions of this subpart apply?
- 30.4 What requirements apply to EPA's use of studies in taking final action?
- 30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?
- 30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?
- 30.7 What role does independent peer review play in this section?
- 30.8 How is EPA to account for cost under this subpart?
- 30.9 May the EPA Administrator grant exemptions to this subpart?
- 30.10 What other requirements apply under this subpart?



Authority: Clean Air Act §§ 103, 301(a), 42 U.S.C. §§ 7403, 7601(a); Clean Water Act §§ 104, 501, 33 U.S.C. §§ 1254, 1361; Safe Drinking Water Act §§ 1442, 1450(a)(1), 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act §§ 2002(a)(1), 7009, 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) §§ 115, 311, 42 U.S.C. §§ 9616, 9660; Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048; Federal Insecticide, Fungicide, and Rodenticide Act §§ 25(a)(1), 136r(a), 7 U.S.C. §§ 136r(a), 136w; and Toxic Substances Control Act, as amended, § 10, 15 U.S.C. § 2609.

#### **§30.1 What is the purpose of this subpart?**

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

#### **§30.2 What definitions apply to this subpart?**

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

*Dose response data and models* means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions

typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

*Pivotal regulatory science* means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

*Regulatory decisions* mean final regulations determined to be “significant regulatory actions” by the Office of Management and Budget pursuant to Executive Order 12866.

*Regulatory science* means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

*Research data* means “research data” as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

### **§30.3 How do the provisions of this subpart apply?**

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of

this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

#### **§30.4 What requirements apply to EPA's use of studies in taking final action?**

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

#### **§30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?**

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered "publicly available in a manner sufficient for independent validation" when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

- (a) Data (where necessary, data would be made available subject to access and use restrictions).
- (b) Associated protocols necessary to understand, assess, and extend conclusions;
- (c) Computer codes and models involved in the creation and analysis of such information;
- (d) Recorded factual materials; and
- (e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

**§30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?**

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default

assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

#### **§30.7 What role does independent peer review in this section?**

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions*, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

#### **§30.8 How is EPA to account for cost under this subpart?**

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

**§30.9 May the EPA Administrator grant exemptions to this subpart?**

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

- (a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or
- (b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

**§30.10 What other requirements apply under this subpart?**

EPA shall implement the provisions of this section consistent with the definition of “research data” in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

Message

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**From:** Bolen, Brittany [bolen.brittany@epa.gov]  
**Sent:** 4/24/2018 5:26:22 PM  
**To:** Woods, Clint [woods.clint@epa.gov]; Schwab, Justin [Schwab.Justin@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bowman, Liz [Bowman.Liz@epa.gov]; Jackson, Ryan [jackson.ryan@epa.gov]; Leopold, Matt [Leopold.Matt@epa.gov]  
**Subject:** FW: Strengthening Transparency in Regulatory Science  
**Attachments:** Data Access Draft\_signature 4 24.docx

For your records, attached is the final word document that is being printed for signature.

Thanks,  
Brittany

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**From:** Nickerson, William  
**Sent:** Tuesday, April 24, 2018 1:24 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Subject:** Strengthening Transparency in Regulatory Science

The signature version



**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 30**

**[EPA-HQ-OA-2018-0259; FRL-XXXX-XX]**

**RIN 2080-AA14**

**Strengthening Transparency in Regulatory Science**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

**DATES:** Comments must be received on or before **[insert date 30 days after date of publication in the Federal Register]**.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OA-2018-0259, at [https:// www.regulations.gov](https://www.regulations.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a

written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit [https://www.epa.gov/dockets/ commenting-epa-dockets](https://www.epa.gov/dockets/commenting-epa-dockets).

**FOR FURTHER INFORMATION, CONTACT:** Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-0221; email address: [ HYPERLINK "mailto:sinks.tom@epa.gov" ].

**SUPPLEMENTARY INFORMATION:**

*Submitting CBI.* Do not submit information that you consider to be CBI electronically through <https://www.regulations.gov> or email. Send or deliver information identified as CBI to only the following address using U.S Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA–HQ–OA-2018-0259, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For other methods of delivery, see [ HYPERLINK "https://www.epa.gov/dockets/where-send-comments-epa-dockets" ].

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

*Organization of This Document.* The following outline is provided to aid in locating information in this preamble.

- I. General Information
  - A. Does this Action Apply to Me?
  - B. What action is the Agency taking?
  - C. What is the Agency's Authority for taking this action?
- II. Background
- III. Request for Comment
- IV. Statutory and Executive Orders

**I. General Information**

*A. Does this action apply to me?*

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

*B. What action is the agency taking?*

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

*C. What is the agency's authority for taking this action?*

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048;

Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

## **II. Background**

The best available science must serve as the foundation of EPA's regulatory actions.<sup>1</sup> Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency is enhancing the public's ability to understand and meaningfully participate in the regulatory process.<sup>2</sup> In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models

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<sup>1</sup> See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

<sup>2</sup> See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

underlying scientific studies that are pivotal to the regulatory action are available to the public.

This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.<sup>3</sup> This proposed rule is also consistent with Executive Orders 13777<sup>4</sup> and 13783,<sup>5</sup> and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*<sup>6</sup> (the Guidelines) and OMB Memorandum 13-13: *Open Data Policy – Managing Information as an Asset*.<sup>7</sup> It builds upon prior EPA actions<sup>8</sup> in

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<sup>3</sup> EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

<sup>4</sup> Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

<sup>5</sup> Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

<sup>6</sup> February 22, 2002 (67 F.R. 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) [ [HYPERLINK "https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information"](https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information) ].

<sup>7</sup> *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* ([ [HYPERLINK "https://project-open-data.cio.gov/policy-memo/"](https://project-open-data.cio.gov/policy-memo/) ]). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

<sup>8</sup> [ [HYPERLINK "https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransparencyplan.pdf"](https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransparencyplan.pdf) ] \t "\_blank" ]; [ [HYPERLINK "https://www.epa.gov/open/epa-open-government-plan-40"](https://www.epa.gov/open/epa-open-government-plan-40) ]; [ [HYPERLINK "https://www.epa.gov/open/us-environmental-protection-agency-open-data-policy-implementation-plan"](https://www.epa.gov/open/us-environmental-protection-agency-open-data-policy-implementation-plan) ] \t "\_blank" ]; EPA's [ [HYPERLINK "https://www.epa.gov/sites/production/files/2014-02/documents/scientific\\_integrity\\_policy\\_2012.pdf"](https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf) ]; [

response to government-wide data access and sharing policies, as well as the experience of other federal agencies in this space.<sup>9</sup> In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.<sup>10</sup> These policies are informed by the policies recently adopted by some major scientific journals,<sup>11</sup> spurred in some part by the “replication crisis.”<sup>12</sup>

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling “pivotal regulatory science.” “Pivotal regulatory science” is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of

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HYPERLINK "<https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>" ] ;

<sup>9</sup> For example, see related policies from the [ HYPERLINK "<https://www.nsf.gov/bfa/dias/policy/dmp.jsp>" ], [ HYPERLINK "<https://www.nist.gov/open>" ], the [ HYPERLINK "<https://grants.nih.gov/policy/sharing.htm>" ]; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure ([ HYPERLINK "<https://www.census.gov/fsrdc>" ]).

<sup>10</sup> These include policies and recommendations from: the [ HYPERLINK "<https://www.acus.gov/research-projects/science-administrative-process>" ]; National Academies’ reports on [ HYPERLINK "<https://www.nap.edu/read/9958>" ], [ HYPERLINK "<https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities>" ], and [ HYPERLINK "<https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing>" ]; the [ HYPERLINK "<https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing>" ]; [ HYPERLINK "[https://osf.io/x2w9h/?\\_ga=2.15543670.1160736397.1518527893-776332106.1518527893](https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893)" ]; [ HYPERLINK "[http://www.isrtp.org/GMU%20WEBINAR\\_DEC\\_2013/GMU%20Study%20Document4.pdf](http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf)" ]; and the [ HYPERLINK "<http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf>" ].

<sup>11</sup> For example, see related policies from the [ HYPERLINK "<http://www.pnas.org/page/authors/journal-policies>" \ "xi" ], [ HYPERLINK "<http://journals.plos.org/plosone/s/data-availability>" ], [ HYPERLINK "<http://www.sciencemag.org/authors/science-journals-editorial-policies>" ], and [ HYPERLINK "<http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf>" ].

<sup>12</sup> See: [ HYPERLINK "<https://www.nature.com/articles/s41562-016-0021>" ]; [ HYPERLINK "<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124>" ]; [ HYPERLINK "<http://science.sciencemag.org/content/343/6168/229.long>" ]; [ HYPERLINK "<https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong>" ].; [ HYPERLINK "<http://stm.sciencemag.org/content/8/341/341ps12.full>" ]

a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying “pivotal regulatory science”) is available to the public for validation<sup>13</sup> in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis.

Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA’s regulatory science should be consistent with the Office of Management and Budget’s *Final Information Quality Bulletin for Peer Review*.<sup>14</sup>

Robust peer review plays a critical role in independently validating key findings and ensuring

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<sup>13</sup> EPA has not consistently followed previous EPA policy (e.g, EPA’s Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

<sup>14</sup> <https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf>



that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: a broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines<sup>15</sup> (which apply to "third party" information - e.g., non-government scientific research – if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will

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<sup>15</sup> February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) [ HYPERLINK "<https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information>" ]

lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government.<sup>16</sup> Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.<sup>17</sup> The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach."<sup>18</sup> More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy<sup>19</sup> have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range

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<sup>16</sup> See examples from the [ [HYPERLINK "https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html"](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html) ], [ [HYPERLINK "https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf"](https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf) ], [ [HYPERLINK "https://studentprivacy.ed.gov/sites/default/files/resource\\_document/file/data\\_deidentification\\_terms.pdf"](https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf) ],

and the [ [HYPERLINK "https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html"](https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html) ].

<sup>17</sup> [ [HYPERLINK "https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html"](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html) ].

<sup>18</sup> [ [HYPERLINK "https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities"](https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities) ].

<sup>19</sup> [ [HYPERLINK "https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf"](https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf) ]; [ [HYPERLINK "https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy"](https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy) ]; [ [HYPERLINK "https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps"](https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps) ].

from deposition in public data repositories, consistent with requirements for many scientific journals,<sup>20</sup> to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.<sup>21</sup> EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.<sup>22</sup>

Implementation of this proposed rule will be consistent with the definition of “research data” in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be “significant regulatory actions” pursuant to E.O. 12866. The Agency’s offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

### **III. Request for Comment**

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<sup>20</sup> For example, see policies or recommendations of publishers [ [HYPERLINK "https://authorservices.taylorandfrancis.com/data-repositories/"](https://authorservices.taylorandfrancis.com/data-repositories/) ], [ [HYPERLINK "https://www.elsevier.com/authors/author-services/research-data"](https://www.elsevier.com/authors/author-services/research-data) ], [ [HYPERLINK "http://journals.plos.org/plosone/s/data-availability"](http://journals.plos.org/plosone/s/data-availability) ], and [ [HYPERLINK "https://www.springernature.com/gp/authors/research-data-policy/repositories"](https://www.springernature.com/gp/authors/research-data-policy/repositories) ].

<sup>21</sup> For example: [ [HYPERLINK "https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/"](https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/) ]; [ [HYPERLINK "https://www.census.gov/fsrdc"](https://www.census.gov/fsrdc) ].

<sup>22</sup> These recommendations are consistent with those of Lutter and Zorn (2016). [ [HYPERLINK "https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf"](https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf) ] re

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation. EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above.

EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate.

Although the proposed regulatory text would impose requirements specifically on final regulations determined to be “significant regulatory actions” under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be “major” under the Congressional Review Act, or “economically

significant” under EO 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of “*pivotal regulatory science*,” and “*dose response data and models*” and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies’ policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by

law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

#### **IV. Statutory and Executive Orders Reviews**

##### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:*

###### *Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available

in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies<sup>23</sup> This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy, confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to EO 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: "Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. ..."

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<sup>23</sup> [ [HYPERLINK "https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities"](https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities) ].



They concluded that “an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available.”<sup>24</sup>

*B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is not expected to be an Executive Order 13771 regulatory action because it relates to “agency organization, management or personnel.”

*C. Paperwork Reduction Act (PRA)*

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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<sup>24</sup> [ HYPERLINK "<https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf>" ].

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

*J. National Technology Transfer and Advancement Act[ SEQ CHAPTER \h \r 1] (NTTAA)*

This rulemaking does not involve technical standards.

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

**Strengthening Transparency in Regulatory Science**  
**Page 19 of 27**

**List of Subjects in 40 CFR Part 30**

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements

Dated: \_\_\_\_\_.

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E. Scott Pruitt,  
Administrator

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

**PART 30—Transparency in Regulatory Decisionmaking**

1. Add part 30 to read as follows:

**PART 30—Transparency in Regulatory Decisionmaking**

Sec.

- 30.1 What is the purpose of this subpart?
- 30.2 What definitions apply to this subpart?
- 30.3 How do the provisions of this subpart apply?
- 30.4 What requirements apply to EPA’s use of studies in taking final action?
- 30.5 What requirements apply to EPA’s use of dose response data and models underlying pivotal regulatory science?
- 30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?
- 30.7 What role does independent peer review play in this section?
- 30.8 How is EPA to account for cost under this subpart?
- 30.9 May the EPA Administrator grant exemptions to this subpart?
- 30.10 What other requirements apply under this subpart?

Authority: Clean Air Act §§ 103, 301(a), 42 U.S.C. §§ 7403, 7601(a); Clean Water Act §§ 104, 501, 33 U.S.C. §§ 1254, 1361; Safe Drinking Water Act §§ 1442, 1450(a)(1), 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act §§ 2002(a)(1), 7009, 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) §§ 115, 311, 42 U.S.C. §§ 9616, 9660; Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048; Federal Insecticide, Fungicide, and Rodenticide Act §§ 25(a)(1), 136r(a), 7 U.S.C. §§ 136r(a), 136w; and Toxic Substances Control Act, as amended, § 10, 15 U.S.C. § 2609.

### **§30.1 What is the purpose of this subpart?**

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

### **§30.2 What definitions apply to this subpart?**

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

*Dose response data and models* means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions

typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

*Pivotal regulatory science* means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

*Regulatory decisions* mean final regulations determined to be “significant regulatory actions” by the Office of Management and Budget pursuant to Executive Order 12866.

*Regulatory science* means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

*Research data* means “research data” as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

### **§30.3 How do the provisions of this subpart apply?**

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of

this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

#### **§30.4 What requirements apply to EPA’s use of studies in taking final action?**

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

#### **§30.5 What requirements apply to EPA’s use of dose response data and models underlying pivotal regulatory science?**

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered “publicly available in a manner sufficient for independent validation” when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

- (a) Data (where necessary, data would be made available subject to access and use restrictions).
- (b) Associated protocols necessary to understand, assess, and extend conclusions;
- (c) Computer codes and models involved in the creation and analysis of such information;
- (d) Recorded factual materials; and
- (e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

**§30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?**

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default



assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

#### **§30.7 What role does independent peer review in this section?**

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions*, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

#### **§30.8 How is EPA to account for cost under this subpart?**

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

**§30.9 May the EPA Administrator grant exemptions to this subpart?**

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

- (a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or
- (b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

**§30.10 What other requirements apply under this subpart?**

EPA shall implement the provisions of this section consistent with the definition of “research data” in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

Message

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**From:** Bowman, Liz [Bowman.Liz@epa.gov]  
**Sent:** 4/24/2018 6:04:44 PM  
**To:** Bolen, Brittany [bolen.brittany@epa.gov]  
**CC:** Woods, Clint [woods.clint@epa.gov]; Schwab, Justin [Schwab.Justin@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Jackson, Ryan [jackson.ryan@epa.gov]; Leopold, Matt [Leopold.Matt@epa.gov]  
**Subject:** RE: Strengthening Transparency in Regulatory Science

A signed copy would be better

---

**From:** Bolen, Brittany  
**Sent:** Tuesday, April 24, 2018 2:04 PM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>  
**Subject:** Re: Strengthening Transparency in Regulatory Science

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Sent from my iPhone

On Apr 24, 2018, at 2:02 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Is someone putting this on the website, so that the press release can link to it?

---

**From:** Bolen, Brittany  
**Sent:** Tuesday, April 24, 2018 1:26 PM  
**To:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Schwab, Justin <[Schwab.Justin@epa.gov](mailto:Schwab.Justin@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Leopold, Matt <[Leopold.Matt@epa.gov](mailto:Leopold.Matt@epa.gov)>  
**Subject:** FW: Strengthening Transparency in Regulatory Science

For your records, attached is the final word document that is being printed for signature.

Thanks,  
Brittany

---

**From:** Nickerson, William  
**Sent:** Tuesday, April 24, 2018 1:24 PM  
**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Subject:** Strengthening Transparency in Regulatory Science

The signature version

**From:** EPA Press Office [press=epa.gov@cmail19.com]  
**on behalf of** EPA Press Office [press@epa.gov]  
**Sent:** 4/24/2018 6:30:03 PM  
**To:** Beck, Nancy [Beck.Nancy@epa.gov]  
**Subject:** EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations



U.S. ENVIRONMENTAL PROTECTION AGENCY  
**NEWS RELEASE**  
WWW.EPA.GOV/NEWSROOM

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## **EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations**

**WASHINGTON** (April 24, 2018) - Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and that underlying scientific information is publicly available in a manner sufficient for independent validation.

**“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt.** “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s *Science for Policy Project* and the Administrative Conference of the United States’ *Science in the Administrative Process Project*.

The proposed rule builds upon President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”

- ♦ **Executive Order 13783**, also issued in March 2017, provides that “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** “The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process.”

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the Journal *Risk Analysis*:** “I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** “EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says

justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** “IDEM supports transparency in rulemaking. Good, sound science leads to better regulations.”

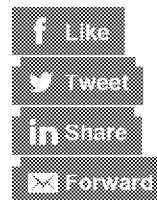
**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 - 1996):** “In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

###

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1200 Pennsylvania Avenue Northwest  
Washington, D.C. 20004



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Message

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**From:** Bolen, Brittany [bolen.brittany@epa.gov]  
**Sent:** 4/24/2018 9:57:47 PM  
**To:** Beck, Nancy [Beck.Nancy@epa.gov]  
**Subject:** RE: SIGNED: Strengthening Transparency in Regulatory Science

Of course. Should be on our website now.

---

**From:** Beck, Nancy  
**Sent:** Tuesday, April 24, 2018 3:38 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Subject:** RE: SIGNED: Strengthening Transparency in Regulatory Science

Thanks. Can I share with my staff?

---

Nancy B. Beck, Ph.D., DABT  
Deputy Assistant Administrator, OCSPP  
P: 202-564-1273  
M: 202-731-9910  
[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)

---

**From:** Bolen, Brittany  
**Sent:** Tuesday, April 24, 2018 3:20 PM  
**To:** Schwab, Justin <[Schwab.Justin@epa.gov](mailto:Schwab.Justin@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science

---

**From:** Johnson, Laura-S  
**Sent:** Tuesday, April 24, 2018 3:10 PM  
**To:** Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Lyons, Troy <[lyons.troy@epa.gov](mailto:lyons.troy@epa.gov)>; Bennett, Tate <[Bennett.Tate@epa.gov](mailto:Bennett.Tate@epa.gov)>; White, Elizabeth <[white.elizabeth@epa.gov](mailto:white.elizabeth@epa.gov)>; Bodine, Susan <[bodine.susan@epa.gov](mailto:bodine.susan@epa.gov)>; Minoli, Kevin <[Minoli.Kevin@epa.gov](mailto:Minoli.Kevin@epa.gov)>; Leopold, Matt <[Leopold.Matt@epa.gov](mailto:Leopold.Matt@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Wheeler, Andrew <[wheeler.andrew@epa.gov](mailto:wheeler.andrew@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Wooden-Aguilar, Helena <[Wooden-Aguilar.Helena@epa.gov](mailto:Wooden-Aguilar.Helena@epa.gov)>; Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>; Richardson, RobinH <[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>; Hope, Brian <[Hope.Brian@epa.gov](mailto:Hope.Brian@epa.gov)>; Fonseca, Silvina <[Fonseca.Silvina@epa.gov](mailto:Fonseca.Silvina@epa.gov)>; Hewitt, James <[hewitt.james@epa.gov](mailto:hewitt.james@epa.gov)>; Abboud, Michael <[abboud.michael@epa.gov](mailto:abboud.michael@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Gaines, Cynthia <[Gaines.Cynthia@epa.gov](mailto:Gaines.Cynthia@epa.gov)>; Nickerson, William <[Nickerson.William@epa.gov](mailto:Nickerson.William@epa.gov)>; Lovell, Will (William) <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)>; Kime, Robin <[Kime.Robin@epa.gov](mailto:Kime.Robin@epa.gov)>; Maguire, Kelly <[Maguire.Kelly@epa.gov](mailto:Maguire.Kelly@epa.gov)>; Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon

Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of



compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,  
Laura

Laura S. Johnson | U.S. Environmental Protection Agency  
Special Assistant, Office of the Administrator | Cell (202) 819-4941  
Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

Message

---

**From:** Bowman, Liz [Bowman.Liz@epa.gov]  
**Sent:** 4/24/2018 9:59:24 PM  
**To:** Woods, Clint [woods.clint@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Jackson, Ryan [jackson.ryan@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Schwab, Justin [Schwab.Justin@epa.gov]  
**CC:** Wilcox, Jahan [wilcox.jahan@epa.gov]  
**Subject:** RE: 'secret science' proposal

Awesome, thank you!

---

**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 5:36 PM  
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>  
**Cc:** Wilcox, Jahan <wilcox.jahan@epa.gov>  
**Subject:** RE: 'secret science' proposal

Short answer is it applies prospectively to future regulations. Long answer below:

From the preamble:

This proposed regulation is intended to apply prospectively to final regulations... The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

Worth noting:

EO 13777 on reg reform calls on ref reform task forces to identify for repeal/replace/modify existing "regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

Proposed rule also requests comment on:

- EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions.
- For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record.
- EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date.
- In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.

---

**From:** Beck, Nancy  
**Sent:** Tuesday, April 24, 2018 5:29 PM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>

**Cc:** Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>

**Subject:** RE: 'secret science' proposal

Looping in Justin

---

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: 202-731-9910

[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)

---

**From:** Bowman, Liz

**Sent:** Tuesday, April 24, 2018 5:17 PM

**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>

**Cc:** Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>

**Subject:** FW: 'secret science' proposal

This is a good question, and one I am sure we will get from others – can this new proposal affect regulations retroactively?

Thank you, Liz

---

**From:** Richard.Valdmanis@thomsonreuters.com [<mailto:Richard.Valdmanis@thomsonreuters.com>]

**Sent:** Tuesday, April 24, 2018 4:45 PM

**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>

**Cc:** [timothy.gardner@thomsonreuters.com](mailto:timothy.gardner@thomsonreuters.com); [valerie.volcovici@thomsonreuters.com](mailto:valerie.volcovici@thomsonreuters.com)

**Subject:** 'secret science' proposal

Liz, Jahan – This may be a very silly question, but I have to ask. Could today's proposed change to the types of research EPA can consider in rule-making be used to rescind existing rules and regulations? In other words, could it be applied retroactively? Or is it specifically for future action?

Thanks kindly,

Rich

Message

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**From:** Schwab, Justin [Schwab.Justin@epa.gov]  
**Sent:** 4/25/2018 3:02:59 PM  
**To:** Bowman, Liz [Bowman.Liz@epa.gov]  
**CC:** Woods, Clint [woods.clint@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Wilcox, Jahan [wilcox.jahan@epa.gov]  
**Subject:** Re: From Washington Post

That's only talking about the transitional period, for rulemaking that are in process at the time this policy will go into effect.

Sent from my iPhone

On Apr 25, 2018, at 10:41 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Can you all help here?

---

**From:** Stromberg, Stephen [<mailto:Stephen.Stromberg@washpost.com>]  
**Sent:** Wednesday, April 25, 2018 10:35 AM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>  
**Cc:** Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>  
**Subject:** RE: From Washington Post

Thanks, Liz. By "The Agency's offices should be guided by this policy to the maximum extent practicable", do you mean that it would not be an iron-clad requirement? That is, if there were no other way to quantify the health effects of air pollution on human beings, the EPA would consider studies that rely on, say, confidential patient information?

Thanks.

Best,  
Steve

Steve Stromberg  
The Washington Post  
Office: (202) 334-6370  
Cell: (310) 770-6646

---

**From:** Bowman, Liz [<mailto:Bowman.Liz@epa.gov>]  
**Sent:** Tuesday, April 24, 2018 6:12 PM  
**To:** Stromberg, Stephen <[Stephen.Stromberg@washpost.com](mailto:Stephen.Stromberg@washpost.com)>  
**Cc:** Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>  
**Subject:** FW: From Washington Post

With regard to the biomass decision, EU to this day recognizes biomass as a carbon neutral form of energy production. California and other states in the North East also recognize that biomass is a carbon neutral form of energy production in their state renewable portfolio standards.

On the proposed science transparency policy: The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

EO 13777 on reg reform calls on task forces to identify for repeal/replace/modify existing "regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

**Proposed rule also requests comment on:**

- EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions.
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- In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.

Thank you – Liz

---

**From:** Stromberg, Stephen [<mailto:Stephen.Stromberg@washpost.com>]

**Sent:** Tuesday, April 24, 2018 1:08 PM

**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>

**Subject:** RE: From Washington Post

Hi Liz,

I had planned on filing this afternoon – at 4 – but I can probably push to tomorrow if that helps.

Thanks.

Best,  
Steve

Steve Stromberg  
The Washington Post  
Office: (202) 334-6370  
Cell: (310) 770-6646

---

**From:** Bowman, Liz [<mailto:Bowman.Liz@epa.gov>]  
**Sent:** Tuesday, April 24, 2018 1:08 PM  
**To:** Stromberg, Stephen <[Stephen.Stromberg@washpost.com](mailto:Stephen.Stromberg@washpost.com)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>  
**Subject:** RE: From Washington Post

[EXTERNAL EMAIL]

Hi Stephen – What is your deadline on this?

---

**From:** Stromberg, Stephen [<mailto:Stephen.Stromberg@washpost.com>]  
**Sent:** Tuesday, April 24, 2018 1:07 PM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>  
**Subject:** From Washington Post

Hi Liz and Jahan,

I'm working on an editorial today about Administrator Pruitt's Monday biomass decision and today's secret science decision. The first ratifies a mistake the Europeans made years ago in how to account for emissions from biomass. The second would throw out long-established research and make it difficult/impossible for scientifically valid work to be included in EPA decisions. Any response?

Thanks.

Best,  
Steve

Steve Stromberg  
The Washington Post  
Office: (202) 334-6370  
Cell: (310) 770-6646

Message

---

**From:** Woods, Clint [woods.clint@epa.gov]  
**Sent:** 4/25/2018 3:14:15 PM  
**To:** Bowman, Liz [Bowman.Liz@epa.gov]  
**CC:** Schwab, Justin [Schwab.Justin@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Wilcox, Jahan [wilcox.jahan@epa.gov]  
**Subject:** Re: From Washington Post

That language is combined with point in preamble that the rule, if finalized, would apply to future regulations.

On Apr 25, 2018, at 10:41 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Can you all help here?

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**Subject:** RE: From Washington Post

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**Sent:** Tuesday, April 24, 2018 6:12 PM  
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Thank you – Liz

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**Sent:** Tuesday, April 24, 2018 1:08 PM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>  
**Subject:** RE: From Washington Post

Hi Liz,

I had planned on filing this afternoon – at 4 – but I can probably push to tomorrow if that helps.

Thanks.

Best,  
Steve

Steve Stromberg  
The Washington Post  
Office: (202) 334-6370  
Cell: (310) 770-6646

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**Sent:** Tuesday, April 24, 2018 1:08 PM  
**To:** Stromberg, Stephen <[Stephen.Stromberg@washpost.com](mailto:Stephen.Stromberg@washpost.com)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>  
**Subject:** RE: From Washington Post



[EXTERNAL EMAIL]

Hi Stephen – What is your deadline on this?

---

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**Sent:** Tuesday, April 24, 2018 1:07 PM

**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>

**Subject:** From Washington Post

Hi Liz and Jahan,

I'm working on an editorial today about Administrator Pruitt's Monday biomass decision and today's secret science decision. The first ratifies a mistake the Europeans made years ago in how to account for emissions from biomass. The second would throw out long-established research and make it difficult/impossible for scientifically valid work to be included in EPA decisions. Any response?

Thanks.

Best,  
Steve

Steve Stromberg  
The Washington Post  
Office: (202) 334-6370  
Cell: (310) 770-6646

Message

---

**From:** Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]  
**Sent:** 4/24/2018 4:58:52 PM  
**To:** Nickerson, William [Nickerson.William@epa.gov]  
**CC:** Corrales, Mark [Corrales.Mark@epa.gov]; Curry, Bridgid [Curry.Bridgid@epa.gov]; Lamson, Amy [Lamson.Amy@epa.gov]; Kime, Robin [Kime.Robin@epa.gov]; Maguire, Kelly [Maguire.Kelly@epa.gov]  
**Subject:** RE: requesting approval to send an action to signature (time sensitive)

Bill,  
This action is approved to send for signature.  
Thank you,  
Brittany

---

**From:** Nickerson, William  
**Sent:** Tuesday, April 24, 2018 12:57 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Cc:** Corrales, Mark <Corrales.Mark@epa.gov>; Curry, Bridgid <Curry.Bridgid@epa.gov>; Lamson, Amy <Lamson.Amy@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>  
**Subject:** requesting approval to send an action to signature (time sensitive)

Brittany,

Very shortly, I expect OMB to formally clear the proposal for Strengthening Transparency in Regulatory Science. I understand the Administrator has a signing ceremony planned for later this afternoon, and am requesting your approval to send this forward for signature as soon as we get OMB clearance. Let me know if you would like additional information. Thank you.

Bill

William (Bill) Nickerson  
Associate Office Director  
Office of Regulatory Policy and Management  
Office of Policy  
Phone: (202) 566-0326

Message

---

**From:** Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]  
**Sent:** 4/25/2018 7:02:22 PM  
**To:** Lovell, Will (William) [lovell.william@epa.gov]  
**Subject:** Re: Updated the TPs to include transparency

Thanks, Will!

On Apr 25, 2018, at 2:24 PM, Lovell, Will (William) <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)> wrote:

Please see attached. 24 and 41 is still correct.

New sub-bullet: "On April 24, Administrator Pruitt signed a proposed rule to ensure that our regulatory science is transparent and publicly available in a manner sufficient for independent validation."

**Will Lovell**  
Policy Advisor, Office of Policy  
U.S. Environmental Protection Agency  
(202) 564-5713  
[Lovell.William@epa.gov](mailto:Lovell.William@epa.gov)

<Reg Reform TPs 04.25.2018.docx>

Message

---

**From:** Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]  
**Sent:** 4/25/2018 7:02:12 PM  
**To:** Jackson, Ryan [jackson.ryan@epa.gov]  
**Subject:** Fwd: Updated the TPs to include transparency  
**Attachments:** Reg Reform TPs 04.25.2018.docx; ATT00001.htm

Begin forwarded message:

**From:** "Lovell, Will (William)" <lovell.william@epa.gov>  
**Date:** April 25, 2018 at 2:24:26 PM EDT  
**To:** "Bolen, Brittany" <bolen.brittany@epa.gov>  
**Subject:** Updated the TPs to include transparency

Please see attached. 24 and 41 is still correct.

New sub-bullet: "On April 24, Administrator Pruitt signed a proposed rule to ensure that our regulatory science is transparent and publicly available in a manner sufficient for independent validation."

**Will Lovell**  
Policy Advisor, Office of Policy  
U.S. Environmental Protection Agency  
(202) 564-5713  
[Lovell.William@epa.gov](mailto:Lovell.William@epa.gov)

- As we implement regulatory reform at EPA, our vision is to return the agency back to the basics of its core mission – to protect human health and the environment.
- We are effectively meeting our statutory deadlines (e.g., TSCA implementation) while correcting the wrongs of the previous administration, which involves the complex process of navigating the administrative state.
- After the previous administration, we had a lot of work to do. According to OMB, over the last decade, EPA regulations imposed annual costs of **\$43.2 to \$50.9 billion** – more than the cost of all other federal agencies *combined*. Over that same period, EPA issued more major rules than *any* other federal agency.
- When President Trump came into office, he recognized America’s need for regulatory relief. That’s why, on January 30, 2017, the President signed E.O. 13771, which required federal agencies to finalize 2 deregulatory actions for each new regulatory action. I am proud to say that EPA met this requirement in 2017 and we plan to meet it again in 2018.
- During this process so far, we have finalized **24** deregulatory actions that saved the American people more than **\$1 billion** in regulatory costs. We have also initiated work on an additional 41 deregulatory actions and announced the reconsideration of over a dozen other regulations.
- In our first year, we sought to extend the compliance deadlines of rules we were reconsidering to protect against stranded assets. Now we are mostly engaged in the more difficult work of substantively updating or rewriting past rules. For example:
  - **CPP**: In October 2017, EPA issued a proposed repeal of the CPP saving up to **\$33.3 billion** in 2030. In December, the agency issued an ANPRM for a potential future rulemaking to limit GHG emissions from existing power plants.
  - **WOTUS**: In June 2017, EPA and the U.S. Army Corps of Engineers issued a proposed repeal of the WOTUS rule, which could produce up to **\$476.2 million** in annualized cost-savings. In January 2018, the agencies issued a final rule to delay the WOTUS rule by 2 years to ensure that it does not go into effect before we can reconsider the rule. We are on track to send a Step 2 proposed rule to OMB by May 1.
  - **RMP**: In June 2017, EPA issued a final rule extending the effective date of the RMP rule by 22 months. In March 2018, EPA sent a draft reconsideration rule to OMB for review.
- In addition, EPA has implemented cross-cutting improvements:
  - In October, Administrator Pruitt issued an agency-wide directive to end “sue and settle” practices within the agency, putting an end to regulation by litigation.
  - Later that month, he issued a directive to ensure independence, geographic diversity, and integrity on EPA’s FACs.
  - On April 9, EPA signed the One Federal Decision MOU, which establishes a coordinated and timely process for environmental reviews of major infrastructure projects.
  - On April 24, Administrator Pruitt signed a proposed rule to ensure that our regulatory science is transparent and publicly available in a manner sufficient for independent validation.
- Future actions will include efforts to improve how EPA evaluates the costs and benefits of its rules.

Message

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**From:** Schwab, Justin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EED0F609C0944CC2BBDB05DF3A10AADB-SCHWAB, JUS]  
**Sent:** 4/24/2018 7:47:13 PM  
**To:** Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]  
**Subject:** Fwd: SIGNED: Strengthening Transparency in Regulatory Science  
**Attachments:** Strengthening Transparency in Regulatory Science 04-24-2018.pdf; ATT00001.htm

And in PDF ...

Sent from my iPhone

Begin forwarded message:

**From:** "Bolen, Brittany" <bolen.brittany@epa.gov>  
**To:** "Schwab, Justin" <Schwab.Justin@epa.gov>, "Beck, Nancy" <Beck.Nancy@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>  
**Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science

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**From:** Johnson, Laura-S  
**Sent:** Tuesday, April 24, 2018 3:10 PM  
**To:** Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>  
**Cc:** Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>  
**Subject:** SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon

Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,  
Laura

Laura S. Johnson | U.S. Environmental Protection Agency  
Special Assistant, Office of the Administrator | Cell (202) 819-4941  
Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

Message

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**From:** Yamada, Richard (Yujiro) [yamada.richard@epa.gov]  
**Sent:** 4/23/2018 9:51:15 PM  
**To:** Schwab, Justin [Schwab.Justin@epa.gov]  
**Subject:** Fwd: For Review: Science Transparency News Release

FYI see below

Sent from my iPhone

Begin forwarded message:

**From:** "Ringel, Aaron" <ringel.aaron@epa.gov>  
**Date:** April 23, 2018 at 5:46:24 PM EDT  
**To:** "Palich, Christian" <palich.christian@epa.gov>  
**Cc:** "Bowman, Liz" <Bowman.Liz@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>, "Baptist, Erik" <Baptist.Erik@epa.gov>, "Beck, Nancy" <Beck.Nancy@epa.gov>, "Gordon, Stephen" <gordon.stephen@epa.gov>, "Letendre, Daisy" <letendre.daisy@epa.gov>, "Konkus, John" <konkus.john@epa.gov>, "Beach, Christopher" <beach.christopher@epa.gov>, "Jackson, Ryan" <jackson.ryan@epa.gov>  
**Subject:** Re: For Review: Science Transparency News Release

Same for Chairman Smith. Will see if I can get a quote.

Sent from my iPhone

On Apr 23, 2018, at 5:38 PM, Palich, Christian <palich.christian@epa.gov> wrote:

Senator Rounds is attending, I'll reach out to see if we can get a quote from him.

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <Bowman.Liz@epa.gov> wrote:

Attached, and below, please find a draft press release, based on the talking points and including the statements of support Clint gathered. I am adding Christian/Aaron, to see if they have any additional support statements from Members of Congress that we could add. I wasn't sure about the quotes from scientific journals, but I think they add weight to the announcement. Also, assuming that this will link to the proposal. The current plan is to release shortly following the event, with photos. The event will be live streamed. Please add anyone else I forgot to copy who should be in the loop. Thank you – Liz



## EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS, ENDS 'SECRET SCIENCE'

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and will require that the underlying scientific information be publicly available, in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis,” in which a significant proportion of published research may be false or not reproducible. Examples of the current data access provisions for authors publishing in major scientific journals:

- Science: “All data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis.”
- Nature: “This policy builds upon our long-standing policy on data availability, which requires that authors make materials, data, code, and associated protocols promptly available to readers without undue qualifications. The preferred way to share large data sets is via public repositories.”
- Proceedings of the National Academy of Sciences: “To allow others to replicate and build on work published in PNAS, authors must make materials, data, and associated protocols, including code and scripts, available to readers.”

EPA’s proposal is consistent with President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, explains that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
- **Executive Order 13783**, also issued in March 2017, states “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental

improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

“The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process,” **said Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts**

“I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science,” **said Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis***. “Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

“EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed,” **said Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law**. “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

“IDEM supports transparency in rulemaking,” **says Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM)**. “Good, sound science leads to better regulations.”

“In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the

public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations,” said **Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 – 1996).**

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<Document1.docx>

Message

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**From:** Palich, Christian [palich.christian@epa.gov]  
**Sent:** 4/23/2018 2:36:37 PM  
**To:** Woods, Clint [woods.clint@epa.gov]  
**CC:** Gordon, Stephen [gordon.stephen@epa.gov]; Ringel, Aaron [ringel.aaron@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]  
**Subject:** Re: Science Event Info

This is great Clint. Thank you!

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 10:30 AM, Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)> wrote:

- EPA is proposing a regulation intended to strengthen the transparency of EPA regulatory science.
- The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should rely on such studies if the data underlying those are publicly available in a manner sufficient for independent validation.
- EPA will be soliciting comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

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**From:** Gordon, Stephen  
**Sent:** Monday, April 23, 2018 10:11 AM  
**To:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Cc:** Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>  
**Subject:** Re: Science Event Info

Clint,

Aaron and Christian are looking to provide the members of Congress they have invited with more information about the event tomorrow.

Can you help the info requested below?

Thanks so much.

On Apr 23, 2018, at 10:00 AM, Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)> wrote:

The specific announcement would be great. Like 3-5 bullet points on the policy we can share with invitees.

Christian R. Palich  
Deputy Associate Administrator

Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 9:58 AM, Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)> wrote:

We should have a run of show done soon, and I will email it to you.

What other info do you need?

On Apr 23, 2018, at 9:48 AM, Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)> wrote:

You have any more info we can share with people on the event tomorrow?

---

**Aaron E. Ringel**

*Deputy Associate Administrator*

*Office of Congressional & Intergovernmental Relations*

*U.S. Environmental Protection Agency*

W: 202.564.4373

[Ringel.Aaron@epa.gov](mailto:Ringel.Aaron@epa.gov)

Message

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**From:** Gordon, Stephen [gordon.stephen@epa.gov]  
**Sent:** 4/23/2018 5:58:26 PM  
**To:** Palich, Christian [palich.christian@epa.gov]  
**CC:** Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Woods, Clint [woods.clint@epa.gov]; Frye, Tony (Robert) [frye.robert@epa.gov]  
**Subject:** RE: Science Transparency

Awesome thanks Christian.

---

**From:** Palich, Christian  
**Sent:** Monday, April 23, 2018 1:17 PM  
**To:** Gordon, Stephen <gordon.stephen@epa.gov>  
**Cc:** Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Frye, Tony (Robert) <frye.robert@epa.gov>  
**Subject:** Fwd: Science Transparency

Senator Rounds attending tomorrow.

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

Begin forwarded message:

**From:** "Tharpe, Amanda (Rounds)" <Amanda\_Tharpe@rounds.senate.gov>  
**Date:** April 23, 2018 at 1:15:02 PM EDT  
**To:** "Palich, Christian" <palich.christian@epa.gov>  
**Subject:** Re: Science Transparency

Hey Christian -

The Senator would like to come tomorrow. Will it be a similar setup as the SAB event in terms of remarks, etc?

Thanks!  
Mandy

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

---

**From:** Palich, Christian  
**Sent:** Monday, April 23, 2018 10:57 AM  
**To:** Tharpe, Amanda (Rounds)  
**Subject:** Re: Science Transparency

Should be done around 230. No later than 245.

Christian R. Palich

Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 10:55 AM, Tharpe, Amanda (Rounds) <[Amanda\\_Tharpe@rounds.senate.gov](mailto:Amanda_Tharpe@rounds.senate.gov)> wrote:

Thanks Christian, I'll check. Do you know how long the event is estimated to take?

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**From:** Palich, Christian [<mailto:palich.christian@epa.gov>]  
**Sent:** Monday, April 23, 2018 10:34 AM  
**To:** Tharpe, Amanda (Rounds) <[Amanda\\_Tharpe@rounds.senate.gov](mailto:Amanda_Tharpe@rounds.senate.gov)>  
**Subject:** Re: Science Transparency

It is for 2pm and we would love to have you and the Senator come! Below is some more details. Let me know when you can and we can add him to the run of show.

- EPA is proposing a regulation intended to strengthen the transparency of EPA regulatory science.
- The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should rely on such studies if the data underlying those are publicly available in a manner sufficient for independent validation.
- EPA will be soliciting comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: 202.306.4656

Sent from my iPhone

On Apr 23, 2018, at 10:29 AM, Tharpe, Amanda (Rounds) <[Amanda\\_Tharpe@rounds.senate.gov](mailto:Amanda_Tharpe@rounds.senate.gov)> wrote:

Hey Christian –

Is the science transparency event still on the calendar for tomorrow? Will it be a similar setup to the SAB event?

Thanks!  
Mandy

**Amanda L. Tharpe**  
Deputy Legislative Director and Counsel  
Senator Mike Rounds (SD)  
202-224-5842  
502 Hart Senate Office Building

<image001.jpg><image002.jpg><image003.jpg><image004.jpg><image005.jpg>



Message

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**From:** Abboud, Michael [abboud.michael@epa.gov]  
**Sent:** 4/24/2018 8:16:00 PM  
**To:** Woods, Clint [woods.clint@epa.gov]  
**Subject:** RE: TPs

Thanks man!

---

**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 4:14 PM  
**To:** Abboud, Michael <abboud.michael@epa.gov>  
**Subject:** TPs

- Concerns about the release of private or confidential information are misguided – This action would not require the disclosure of any information and there are a variety of tools to ensure that validation and analysis can be conducted without privacy issues.
  - The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that “Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.”
  - Numerous federal agencies provide de-identification of personal information. The Department of Health and Human Services recently released guidelines to de-identify much more sensitive medical information.
  - Dr. Tony Cox, who chairs EPA’s Clean Air Scientific Advisory Committee and edits the journal, *Risk Analysis*, has testified: “This technical problem is best addressed by technical solutions, and many excellent ones are now available to allow statisticians to do valid analyses while protecting individual data.... These methods, such as multiple imputation, have already been extensively developed, tested, and successfully applied, at the Census Bureau and elsewhere. So, I think that this concern should be viewed as a bit of a red herring: appropriate technical methods to handle it are already available and are being used in other areas.”

Excerpts from the proposed rule preamble:

“EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government.”<sup>[1]</sup> Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.<sup>[2]</sup> The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that “Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.”<sup>[3]</sup> More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy<sup>[4]</sup> have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

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<sup>[1]</sup> See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

<sup>[2]</sup> <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>.

<sup>[3]</sup> <https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities>.

<sup>[4]</sup> <https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf>; <https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy>; <https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps>.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,<sup>[5]</sup> to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.<sup>[6]</sup> EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.<sup>[7]</sup>

From the regulatory text:

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered “publicly available in a manner sufficient for independent validation” when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

- (a) data (where necessary, data would be made available subject to access and use restrictions);
- (b) associated protocols necessary to understand, assess, and extend conclusions;
- (c) computer codes and models involved in the creation and analysis of such information;
- (d) recorded factual materials; and
- (e) detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

...

§ 124.223. May the EPA Administrator grant exemptions to this subpart?

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

- (a) it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or
- (b) it is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

§ 124.224. What other requirements apply under this subpart?

EPA shall implement the provisions of this section consistent with the definition of “research data” in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487,

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<sup>[5]</sup> For example, see policies or recommendations of publishers [Taylor & Francis](#), [Elsevier](#), [PLOS](#), and [Springer Nature](#).

<sup>[6]</sup> For example: <https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/>; <https://www.census.gov/fsrdc>.

<sup>[7]</sup> These recommendations are consistent with those of Lutter and Zorn (2016). <https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf> we re

and other applicable federal laws. Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

.....

.....

Message

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**From:** Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]  
**Sent:** 4/24/2018 8:49:17 PM  
**To:** Woods, Clint [woods.clint@epa.gov]  
**Subject:** Re: SIGNED: Strengthening Transparency in Regulatory Science

Thanks Clint. Full day tomorrow. :)

> On Apr 24, 2018, at 4:47 PM, Woods, Clint <woods.clint@epa.gov> wrote:

>  
> Think this is much improved. Looking forward to visiting with the team tomorrow - Thanks!

>  
> From: Bolen, Brittany  
> Sent: Tuesday, April 24, 2018 3:20 PM  
> To: Schwab, Justin <Schwab.Justin@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Woods, Clint <woods.clint@epa.gov>  
> Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

>  
>  
> From: Johnson, Laura-S  
> Sent: Tuesday, April 24, 2018 3:10 PM  
> To: Jackson, Ryan <jackson.ryan@epa.gov<mailto:jackson.ryan@epa.gov>>; Bowman, Liz <Bowman.Liz@epa.gov<mailto:Bowman.Liz@epa.gov>>; Lyons, Troy <lyons.troy@epa.gov<mailto:lyons.troy@epa.gov>>; Bennett, Tate <Bennett.Tate@epa.gov<mailto:Bennett.Tate@epa.gov>>; White, Elizabeth <white.elizabeth@epa.gov<mailto:white.elizabeth@epa.gov>>; Bodine, Susan <bodine.susan@epa.gov<mailto:bodine.susan@epa.gov>>; Minoli, Kevin <Minoli.Kevin@epa.gov<mailto:Minoli.Kevin@epa.gov>>; Leopold, Matt <Leopold.Matt@epa.gov<mailto:Leopold.Matt@epa.gov>>; Bowman, Liz <Bowman.Liz@epa.gov<mailto:Bowman.Liz@epa.gov>>; Wheeler, Andrew <wheeler.andrew@epa.gov<mailto:wheeler.andrew@epa.gov>>; Bolen, Brittany <bolen.brittany@epa.gov<mailto:bolen.brittany@epa.gov>>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov<mailto:Orme-Zavaleta.Jennifer@epa.gov>>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov<mailto:yamada.richard@epa.gov>>  
> Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov<mailto:Wooden-Aguilar.Helena@epa.gov>>; Grantham, Nancy <Grantham.Nancy@epa.gov<mailto:Grantham.Nancy@epa.gov>>; Richardson, RobinH <Richardson.RobinH@epa.gov<mailto:Richardson.RobinH@epa.gov>>; Hope, Brian <Hope.Brian@epa.gov<mailto:Hope.Brian@epa.gov>>; Fonseca, Silvina <Fonseca.Silvina@epa.gov<mailto:Fonseca.Silvina@epa.gov>>; Hewitt, James <hewitt.james@epa.gov<mailto:hewitt.james@epa.gov>>; Abboud, Michael <abboud.michael@epa.gov<mailto:abboud.michael@epa.gov>>; Wilcox, Jahan <wilcox.jahan@epa.gov<mailto:wilcox.jahan@epa.gov>>; Gaines, Cynthia <Gaines.Cynthia@epa.gov<mailto:Gaines.Cynthia@epa.gov>>; Nickerson, William <Nickerson.William@epa.gov<mailto:Nickerson.William@epa.gov>>; Lovell, Will (William) <lovell.william@epa.gov<mailto:lovell.william@epa.gov>>; Kime, Robin <Kime.Robin@epa.gov<mailto:Kime.Robin@epa.gov>>; Maguire, Kelly <Maguire.Kelly@epa.gov<mailto:Maguire.Kelly@epa.gov>>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov<mailto:Blackburn.Elizabeth@epa.gov>>  
> Subject: SIGNED: Strengthening Transparency in Regulatory Science

>  
> Good afternoon  
> Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."  
>  
> This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.  
>  
> In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.  
>  
> Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.  
>  
> Please contact me if you have any questions.  
>  
> Sincerely,  
> Laura  
>

> Laura S. Johnson | U.S. Environmental Protection Agency  
> Special Assistant, Office of the Administrator | Cell (202) 819-4941  
> Office (202) 566-1273 | johnson.laura-s@epa.gov<mailto:johnson.laura-s@epa.gov>  
>  
> <Strengthening Transparency in Regulatory Science 04-24-2018.pdf>

Message

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**From:** Harvey, Reid [Harvey.Reid@epa.gov]  
**Sent:** 4/24/2018 8:52:04 PM  
**To:** Woods, Clint [woods.clint@epa.gov]  
**Subject:** RE: SIGNED: Strengthening Transparency in Regulatory Science

Yes, thanks, appreciate you sharing it with me.

Reid

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**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 4:48 PM  
**To:** Harvey, Reid <Harvey.Reid@epa.gov>  
**Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science

FYI – Think there are definitely some improvements here.

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**From:** Bolen, Brittany  
**Sent:** Tuesday, April 24, 2018 3:20 PM  
**To:** Schwab, Justin <Schwab.Justin@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Woods, Clint <woods.clint@epa.gov>  
**Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science

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**From:** Johnson, Laura-S  
**Sent:** Tuesday, April 24, 2018 3:10 PM  
**To:** Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>  
**Cc:** Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>  
**Subject:** SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon

Today, the Administrator signed the proposed rule “Strengthening Transparency in Regulatory Science.”

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,  
Laura

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Special Assistant, Office of the Administrator | Cell (202) 819-4941  
Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

Message

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**From:** Shoaff, John [Shoaff.John@epa.gov]  
**Sent:** 4/24/2018 9:07:04 PM  
**To:** Woods, Clint [woods.clint@epa.gov]  
**Subject:** Re: SIGNED: Strengthening Transparency in Regulatory Science

Thanks Clint. Will scan and bet OAQPS would be interested if it comes up with your visit tomorrow. Hope trip goes well.

Sent from my iPhone

On Apr 24, 2018, at 4:48 PM, Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)> wrote:

Thanks again for the feedback on this front – Think this is an improvement.

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**From:** Bolen, Brittany  
**Sent:** Tuesday, April 24, 2018 3:20 PM  
**To:** Schwab, Justin <[Schwab.Justin@epa.gov](mailto:Schwab.Justin@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
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**From:** Johnson, Laura-S  
**Sent:** Tuesday, April 24, 2018 3:10 PM  
**To:** Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Lyons, Troy <[lyons.troy@epa.gov](mailto:lyons.troy@epa.gov)>; Bennett, Tate <[Bennett.Tate@epa.gov](mailto:Bennett.Tate@epa.gov)>; White, Elizabeth <[white.elizabeth@epa.gov](mailto:white.elizabeth@epa.gov)>; Bodine, Susan <[bodine.susan@epa.gov](mailto:bodine.susan@epa.gov)>; Minoli, Kevin <[Minoli.Kevin@epa.gov](mailto:Minoli.Kevin@epa.gov)>; Leopold, Matt <[Leopold.Matt@epa.gov](mailto:Leopold.Matt@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto: Bowman.Liz@epa.gov)>; Wheeler, Andrew <[wheeler.andrew@epa.gov](mailto:wheeler.andrew@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Wooden-Aguilar, Helena <[Wooden-Aguilar.Helena@epa.gov](mailto:Wooden-Aguilar.Helena@epa.gov)>; Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>; Richardson, RobinH <[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>; Hope, Brian <[Hope.Brian@epa.gov](mailto:Hope.Brian@epa.gov)>; Fonseca, Silvina <[Fonseca.Silvina@epa.gov](mailto:Fonseca.Silvina@epa.gov)>; Hewitt, James <[hewitt.james@epa.gov](mailto:hewitt.james@epa.gov)>; Abboud, Michael <[abboud.michael@epa.gov](mailto:abboud.michael@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Gaines, Cynthia <[Gaines.Cynthia@epa.gov](mailto:Gaines.Cynthia@epa.gov)>; Nickerson, William <[Nickerson.William@epa.gov](mailto:Nickerson.William@epa.gov)>; Lovell, Will (William) <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)>; Kime, Robin <[Kime.Robin@epa.gov](mailto:Kime.Robin@epa.gov)>; Maguire, Kelly <[Maguire.Kelly@epa.gov](mailto:Maguire.Kelly@epa.gov)>; Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon

Today, the Administrator signed the proposed rule “Strengthening Transparency in Regulatory Science.”

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.



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Laura

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